

REMARKS

Claims 1 and 75-79 were again rejected pursuant to 35 U.S.C. §103(a) as obvious based upon Bechai et al. (U.S. Patent No. 4,417,583) or Iinuma (U.S. Patent No. 5,450,850) in further view of Seward et al. (U.S. Patent No. 5,699,805) and/or Eberle et al. (U.S. Patent No. 5,368,037).

Claim 1 recites a catheter comprising a body having a longitudinal axis, a circumference and a distal end region; and first and second ultrasonic transducer arrays disposed in the distal end region of the body where the body is adapted for insertion into a blood stream. A person of ordinary skill in the art would not have found the catheter of claim 1 obvious from Bechai et al. or Iinuma in further view of Seward et al. and/or Eberle et al.

Bechai et al. and Iinuma both disclose array structures designed for transesophageal (TEE) probes (Bechai et al. – title and col. 1, lines 9-11; Iinuma – col. 12, line 62 – col. 13, line 10). While generally being small (see Bechai et al. “similar in size to a fiber optic probe” at col. 1, lines 44-47), TEE probes are adapted for use in the esophagus, making such probes “very convenient from the viewpoint of operability and cost” (Iinuma – col. 13, lines 1-2). The use of TEE probes has a further advantage taught by Iinuma – “examination can be performed non-invasively,” avoiding worry and mental burden by the patient (col. 14, lines 49-53). *Bechai, et al. and Iinuma do not teach multiple arrays on a body for insertion into a blood stream.*

Seward et al. disclose a catheter for intravascular use - under fluid imaging of intraluminal/intracavitary use (col. 1, lines 13-16, 23-28 and 39-42). The body is designed for use within the intravenous system given the thinness and length (col. 5, lines 32-35). Seward et al. even note that non-catheter systems include endoscopes or other instruments for use not in confined tortuous pathways (col. 1, lines 28-34). Different uses of the intravascular catheter are noted (see col. 4, lines 62-65 and col. 6, lines 11-14), but not different designs. Seward et al. teach an intravascular catheter (see col. 6, lines 14-16) that may be used elsewhere. *Seward, et al. do not suggest multiple arrays in a body for insertion into a blood stream.*

Bechai, et al. and Iinuma use multiple arrays, but in a relatively larger circumference,

shorter length, and less flexible TEE probes. Seward, et al. teach that intravascular probes may be used in the blood stream. A TEE probe is too stiff, short, and large (spacious) for use in the blood stream. *Since adding arrays takes space, a teaching of multiple arrays on a TEE does not teach multiple arrays on a body for insertion into a blood stream.*

A person of ordinary skill in the art would not have used the teachings of Bechai et al. or Iinuma with Seward et al. and/or Eberle et al. Catheters are very long (e.g. 40-130 centimeters) and designed for use in tortuous vessel pathways, but TEE probes are more simply and cost effectively designed for use in a relatively non-tortuous esophagus. Highlighting some differences, use of the probe in the esophagus may require addition of fluids for ultrasound coupling (see Bechai et al. col. 3, lines 6-13), but catheters are designed for under fluid imaging in a vessel. A person of ordinary skill in the art would not have used the transducer array structure of a TEE in a catheter due to the differences in design, including size and flexibility differences.

Second, claim 1 recites the catheter having a body adapted for insertion into the blood stream. The multiple array structures of Bechai et al. and Iinuma are used in the larger, roomier transesophageal probes. The mere teaching of a catheter being used in the esophagus (Seward et al.) does not suggest that multiple arrays for a transesophageal probe would be used in a catheter. Bechai et al. and Iinuma, even given the teaching of Seward et al., are not catheters having bodies adapted for insertion into the circulatory system.

In the alternative, the Examiner alleges it would have been obvious to provide end or side fire arrays in an intravascular catheter in view of Eberle et al. since these were known to provide scan information from within vessel walls. The Examiner notes the use of catheter in the esophagus in Seward et al.

First, a person of ordinary skill in the art would not have used the TEE structures of Bechai et al. and Iinuma in a catheter of Seward et al. or Eberle since such use is discouraged by Iinuma. As noted by Iinuma, the TEE probes are desirably constructed for non-invasive examination (col. 14, lines 44-53). Iinuma teaches non-invasive use as a benefit, so a person of ordinary skill would not have provided for use of the TEE structure or arrays on an invasive type probe, a catheter.

Second, the repositioning of the array in a catheter (Eberle et al.) does not suggest that

multiple arrays used in larger transesophageal probes (Bechai et al. and Iinuma) would be used in smaller catheters. The background of the above-captioned reissue application notes the different types of arrays used singly in catheters (Col. 1, lines 16-20), including the arrays of Eberle et al. (Col. 1, lines 33-41). Only one type of array is incorporated into these catheters. There is no suggestion to provide multiple arrays in the small intravascular catheters, only in larger transesophageal probes.

The dependent claims 75-79 depend from claim 1, so are allowable for the same reasons.

Claims 2-4, 27-29 and 35-36 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over the references applied to claim 1, or in the case of Bechai et al. further in view of Iinuma. Dependent claims 2-4, 27-29 and 35-36 depend from claim 1, so are allowable for the same reasons. Further limitations distinguish over the cited art. The cited references do not suggest the annular and curved linear arrays claimed in claims 27, 28 and 36.

Claims 5, 30-31, 38-40 and 67 were rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over the references applied to claims 2 and 35 and further in view of Kitney et al. (U.S. Patent No. 5,081,993). Dependent claims 5, 30-31, 38-40 and 67 depend from claim 1 so are allowable for the same reasons.

Further limitations distinguish the cited references. Kitney et al. disclose adjacent rings of elements with common electrical interconnection (Col. 5, lines 60-68). The common electrical connection and operation shows the two annuli of elements as part of a same 2D array. Claim 5 recites two phased arrays separated along the longitudinal axis. Claim 31 claims two types of radial arrays. Kitney et al. do not suggest these limitations of claims 5 and 31. Additionally, a person of ordinary skill in the art would not have used the catheter teachings of Kitney et al. with the TEE probes of Bechai et al. and Iinuma for the reasons discussed above for claim 1. A further reason is provided by Kitney et al. when they note the desire to limit wire leads (col. 5, lines 52-59). A person of ordinary skill would not have added additional separate arrays to a TEE probe structure given the desire to limit the number of wire leads in a catheter, but instead would have expanded one of the arrays.

Claim 67 recites an orientation/position sensor disposed in the distal end region.

Kitney et al. disclose either spark generators or radio opaque dots on the catheter (col. 12, lines 31-64). The x-ray or electrode sensors are outside the patient. The dots or spark generators are not position or orientation sensors, but merely markers to be sensed by external sensors.

Claim 68 was rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over the references applied to claim 67 and further in view of Martinelli (U.S. Patent No. 4,821,731). Claim 68 is allowable for the same reasons as claim 1 and 67. Further, a person of ordinary skill in the art would not have used the magnetic sensor of Martinelli et al. to provide the position sensing of Kitney et al. Kitney et al. determine a 3D position with the sensors external to the patient (see col. 12, lines 30-64). Kitney et al. desire not just the position, but the position relative to an overall picture or view of position (Col. 11, lines 45-61). An x-ray image location using x-ray opaque dots is used. The spark-gap technique provides an overall reference since the sensors are outside and positioned relative to the patient (Figs. 15-16). Martinelli et al. use a fluoroscope for initial position and the magnetic sensor for orientation sensing by pointing the illuminator in the likely direction (co. 11, lines 40-61), not providing an overall view sought by Kitney et al. A person of ordinary skill in the art would not have replaced the 3D position sensor of Kitney et al. with one requiring multiple modes (fluoroscope and magnetic), manual aligning of the illuminator 70 and loss of reference.

Claims 10, 32 and 37 were rejected pursuant to §103(a) as obvious based upon the references applied to claims 2 or 5 or 36 and further in view of Fujio et al. (U.S. Patent No. 5,471,988). Claims 10, 32 and 37 are allowable for the same reasons as claims 1, 2 and 5. Further, Fujio et al. is directed to an endocavity probe (col. 1, lines 13-30; col. 9, lines 28-40; and col. 12, lines 59-63), so would not be used with a catheter for the reasons discussed above for claim 1. Claim 10 recites an array curved around a distal most point of the distal end, but element 374 of Fig. 55 in Fujio et al. only goes "to" the distal end, not around the distal most point.

Claims 7-9 and 11 were rejected pursuant to §103(a) as being unpatentable over Iinuma and Seward et al.

Independent claim 7 claims a catheter with the arrays in the distal end region. As discussed above for claim 1, the teachings Iinuma and Seward et al. would not have been

used to provide these limitations on a catheter. Dependent claims 8, 9 and 11 are allowable for the same reasons.

Claims 20-23 and 63-64 were rejected pursuant to §102(b) as being unpatentable over Iinuma and Seward et al.

Independent claim 20 claims inserting a catheter having a distal end region with first and second phased ultrasonic transducer arrays, and acquiring image information with the arrays. As discussed above for claim 1, the teachings of Iinuma and Seward et al. would not have been used to provide these limitations with a catheter. Dependent claims 21-23 and 63-64 are allowable for the same reasons.

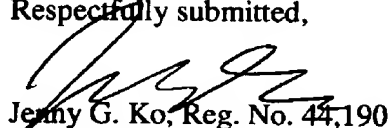
CONCLUSION

Applicants respectfully submit that all of the pending claims 1-76, and 78-79, are in condition for allowance and seeks early allowance thereof. If for any reason, the Reissue Declaration is unacceptable or the Examiner is unable to allow the reissue application but believes that an interview would be helpful to resolve any issues, he is respectfully requested to call Craig A. Summerfield at 312-321-4726.

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